



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office

HM31/0609

DARBY AND DARBY **NOTICE OF ALLOWANCE AND ISSUE FEE DUE**
805 THIRD AVENUE
NEW YORK NY 10022

08/474,450 06/07/95 018 TUNG, J 1634 06/09/98

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|---|-------------|----------------------------|-----------------------------|-------------|
| APPLICATION NO. SHUBER, | FILING DATE | TOTAL CLAIMS ANTHONY F. | EXAMINER AND GROUP ART UNIT | DATE MAILED |
| UNIVERSAL PRIMER SEQUENCE FOR MULTIPLEX DNA AMPLIFICATION | | | | |
| First Named Applicant | | | | |

TITLE OF
INVENTION

1 0372/0B128 435-006.000 F09 UTILITY NO \$1320.00 09/09/98

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|-------------------|----------------|-----------|-------------|--------------|---------|----------|
| ATTY'S DOCKET NO. | CLASS-SUBCLASS | BATCH NO. | APPLN. TYPE | SMALL ENTITY | FEE DUE | DATE DUE |
| | | | | | | |

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED.

THE ISSUE FEE MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED.

HOW TO RESPOND TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

- A. If the status is changed, pay twice the amount of the FEE DUE shown above and notify the Patent and Trademark Office of the change in status, or
- B. If the status is the same, pay the FEE DUE shown above.

If the SMALL ENTITY is shown as NO:

- A. Pay FEE DUE shown above, or
- B. File verified statement of Small Entity Status before, or with, payment of 1/2 the FEE DUE shown above.

II. Part B-Issue Fee Transmittal should be completed and returned to the Patent and Trademark Office (PTO) with your ISSUE FEE. Even if the ISSUE FEE has already been paid by charge to deposit account, Part B Issue Fee Transmittal should be completed and returned. If you are charging the ISSUE FEE to your deposit account, section "4b" of Part B-Issue Fee Transmittal should be completed and an extra copy of the form should be submitted.

III. All communications regarding this application must give application number and batch number. Please direct all communications prior to issuance to Box ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PATENT AND TRADEMARK OFFICE COPY

Notice of Allowability

Application No.

08/474,450

Applicant(s)

Shuber

Examiner

Joyce Tung

Group Art Unit

1634



All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance and Issue Fee Due or other appropriate communication will be mailed in due course.

☒ This communication is responsive to 3/27/98

☒ The allowed claim(s) is/are claims 1-18

☐ The drawings filed on _____ are acceptable.

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

A SHORTENED STATUTORY PERIOD FOR RESPONSE to comply with the requirements noted below is set to EXPIRE **THREE MONTHS** FROM THE "DATE MAILED" of this Office action. Failure to timely comply will result in ABANDONMENT of this application. Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

☐ Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL APPLICATION, PTO-152, which discloses that the oath or declaration is deficient. A SUBSTITUTE OATH OR DECLARATION IS REQUIRED.

☒ Applicant MUST submit NEW FORMAL DRAWINGS

☐ because the originally filed drawings were declared by applicant to be informal.

☒ including changes required by the Notice of Draftsperson's Patent Drawing Review, PTO-948, attached hereto or to Paper No. 21.

☐ including changes required by the proposed drawing correction filed on _____, which has been approved by the examiner.

☐ including changes required by the attached Examiner's Amendment/Comment.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the reverse side of the drawings. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

☐ Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Any response to this letter should include, in the upper right hand corner, the APPLICATION NUMBER (SERIES CODE/SERIAL NUMBER). If applicant has received a Notice of Allowance and Issue Fee Due, the ISSUE BATCH NUMBER and DATE of the NOTICE OF ALLOWANCE should also be included.

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

☐ Interview Summary, PTO-413

☐ Examiner's Amendment/Comment

☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material

☒ Examiner's Statement of Reasons for Allowance

Art Unit: 1634

REASONS FOR ALLOWANCE

1. The following is an examiner's statement of reasons for allowance:

No prior art has been found teaching or suggesting a multiplicity of single-stranded oligonucleotide primer for simultaneous amplification of multiple target DNA sequences under a single set of reaction conditions in a single multiplex PCR in which the primer has a 5' X domain and a 3' Y domain wherein the 5' X domain comprises a common sequence which does not hybridize any one of the multiple target DNA sequences and the 3' Y domain comprises a sequence containing within or flanking one of the target sequence or its complement, the melting temperature is different between different hybrids formed with other 3' Y domain. Further no prior art has been found teaching or suggesting using a multiplicity of single-stranded oligonucleotide primer having a 5' X domain and a 3' Y domain wherein the X domain has SEQ ID NO: 64 in a simultaneous amplification of multiple target DNA sequences reaction. The instant invention can prevent the synthesis of spurious amplification products. The closest prior art is the reference of Weighardt et al. Weighardt et al. teach a tailed oligonucleotide primer which has 5' ends with an unrelated sequence to a target sequence and the 5' end sequence has restriction sites. The method of Weighardt et al can be used in a single step amplification with a single set of primers. However, the instant invention is used in simultaneous amplification of multiple target DNA sequences with a multiplicity of single-stranded oligonucleotide primer.

Art Unit: 1634

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

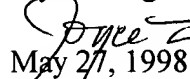
2. Any inquiries concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (703) 305-7112. The examiner can normally be reached on Monday-Friday from 6:30 AM-4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached at (703) 308-1152.

Any inquiries of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

3. Papers related to this application may be submitted to Group 1800 by facsimile transmission. Papers should be faxed to Group 1634 via the PTO Fax Center located in Crystal Mall 1 using (703) 305-3014 or 305-4227. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Joyce Tung


May 27, 1998

KENNETH R. HORLICK
PRIMARY EXAMINER
GROUP 1800 1600 6/8/98

 Kenneth R. Horlick, Ph.D.